DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
Telephone: 781.596.7700
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July 28, 2003

WARNING LETTER

NWE-21-03W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Cynde P. Mitchell, CEO
Browne Trading Company
260 Commercial Street
Portland, ME 04101

Dear Ms. Mitchell:

Between June 24 and 30, 2003, we inspected your seafood processing facility, located at 260 Commercial Street, Portland, ME. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly your vacuum packaged, ready-to-eat, cold smoked fish and scombroid species fish products are adulterated, in that the fishery products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov.

Your deviations were as follows:

Cold Smoking Process & HACCP Plan

You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and include those hazards in your written HACCP plan to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." We recognize that the processing of cold smoked tuna is also covered by a second plan, Fresh Scombroid Forming Species (Group # 2). However, that plan does not provide controls for the hazard of histamine formation during the drying and brining steps of the cold smoked tuna process.

- Two of your processing steps, brining and drying, are carried out over a period of hours. To address the histamine formation hazard during these processing steps, your tuna should be maintained at temperatures below 40 degrees F. Since you have not included any of the processing steps for Cold Smoking in your HACCP plan for histamine forming species, especially the brining and drying steps, and tuna is listed as one of the species that will be cold smoked in your plan, we expect you to include this hazard in your Cold Smoking HACCP plan.

  You are required to have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your HACCP plan for Group #4, Cold Smoked Seafood Vacuum Packed or Packaged in Sealed Containers lists a critical limit ("chilled storage will not exceed [redacted] for more than [redacted]") at the critical control points of raw material and finished product Chilled Storage that is not adequate to control the hazard of *Clostridium botulinum* toxin formation and other pathogens in your vacuum packed and sealed container finished products. Our investigator also reported that although you listed a critical limit of [redacted] for not more than [redacted]" in your plan, your alarms were actually set at 56°F and 58°F respectively. We recognize that you have stated that the alarm is not your primary means of controlling temperatures in this cooler but it is listed in your HACCP plan.

  In addition, our investigator reported the high temperature alarm in your brine cooler was set at 53°F which exceeds your critical limit of [redacted] for not more than [redacted]"

- You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your

firm's HACCP plan for Group #4, Cold Smoked Seafood Vacuum Packed or Packaged in Sealed Containers, lists a monitoring frequency at the raw material cooler, fillet storage cooler (selection cooler), brine cooler, and finished product cooler critical control points that is not adequate to control *Clostridium botulinum* toxin formation and other pathogens in your finished product. Your HACCP plan lists that you will monitor the temperatures in these coolers at least two times per day. We recognize that you actually monitor three times per day. However, FDA recommends that temperatures be monitored continuously.

- You must take an appropriate corrective action when a deviation from your critical limit occurs, to comply with 21 CFR 123.7 (a). However, your firm did not take a corrective action to control pathogen growth and toxin formation when your process for vacuum packaged cold smoked salmon deviated from your critical limit at the chilled storage critical control point. Specifically, our investigator observed vacuum packaged smoked salmon in your finished product storage area with an ambient temperature which exceeded your critical limit of "Chilled storage will not exceed [redacted] for more than [redacted]" Specifically, the same package of vacuum packaged smoked salmon was observed at the following temperatures for three consecutive days: June 24, 51.8°, June 25, 57°F, and June 26, 48.3°F, and you failed to take a corrective action.

Histamine Forming Species Process & HACCP Plan

- You must have a HACCP plan that, at a minimum, lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for Group #2, Fresh Scombroid Toxin Producing Fish, does not list critical limits at receiving that are suitable for the control of scombrotoxin (histamine) formation for those products for which you are the primary processor.

  Because you receive histamine forming species (mackerel and bluefish) directly from the harvest vessels FDA considers you a primary processor. As a primary processor you are responsible for assuring that the histamine forming species you received were not exposed to time temperature abuse prior to your receipt of the fish. FDA recommends one of two control strategies to demonstrate this. The first strategy is to obtain harvest vessel records that show that care was taken on the vessel to cool the fish. The second strategy is to analyze a representative sample of fish received for histamine level. In addition, both strategies include sensory analyses and internal temperatures taken at receipt as part of the critical limit. More specific information on acceptable critical limits can be found in FDA's Fish & Fisheries Products Hazards & Control Guidance: Third

Edition, Chapter 7, pages 88 & 89. This guidance is available on the internet through links at FDA's homepage, www.fda.gov.

Seafood HACCP Sanitation Deviations

- You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the following areas of sanitation with sufficient frequency to ensure control as evidenced by:

  Protection of food, packaging material, and contact surfaces from adulterants:

  - Overspray of water from nearby cleaning operations and backsplash from unsanitized surfaces coming in contact with product and packaging materials.
  - Tuna loins were placed in direct contact with cardboard.
  - Wall and backsplash adjacent to sink used for rinsing fillets inadequately cleaned. Rinse water was observed contacting wall and falling back on fillets.

  Condition and cleanliness of food contact surfaces:

  - Presence of food residue on skinner, slicer, and drying trays.
  - Deeply scored cutting boards that are difficult to clean.
  - Sinks, cutting boards, and wire trays in active use were observed with product residue.
  - The skinner was not sanitized before use on June 26, 2003.

  Prevention of cross-contamination:

  - Inadequate hand washing between handling of raw and cooked product.
  - Product residue on hand contact areas of sink and faucet handles.
  - Product residue remaining on underneath surfaces of smoking trays after cleaning.

- You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your sanitation control records do not cover all eight areas of sanitation. Specifically, none of your sanitation records monitor the safety of the water that comes into contact with food or food contact surfaces; the maintenance of hand washing, hand sanitizing, and toilet facilities; and the protection of food, food packaging material, and food contact surfaces from adulteration with contaminants. Since you chose to create sanitation control records for specific areas of your process, we recommend that you create sanitation control records for your brine cooler.

We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as modifications to the existing HACCP plans for cold smoked seafood and scombroid (histamine-forming) species, and copies of associated monitoring records, or any other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation, and the Good Manufacturing Practice regulation (21 CFR Part 110).

You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Mark Lookabaugh, Compliance Officer, 1 Montvale Avenue, Stoneham, MA 02180. If you have questions regarding any issue in this letter, please contact Mr. Lookabaugh at ***781.596.7751***.

Sincerely,

Gail T. Costello
Director
New England District